



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 524, 556, and 558

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Carprofen; Enrofloxacin; Florfenicol; Tildipirosin; Zilpaterol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during June 2013. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, [george.haibel@fda.hhs.gov](mailto:george.haibel@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during June 2013, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval

(Freedom of Information Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>.

In addition, the animal drug regulations are being amended at 21 CFR 510.600 to correct a sponsor's name and at 21 CFR 556.733 to correct the acceptable daily intake of total residues of tildipirosin. This is being done to improve the accuracy of the regulations.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During June 2013

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
200-524	Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101	Mupirocin Ointment 2%	Original approval as a generic copy of NADA 140-839	524.1465	yes	CE <sup>1</sup>
200-517	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408	ZOBUXA (enrofloxacin) Flavored Antibacterial Tablets	Original approval as a generic copy of NADA 140-441	520.812	yes	CE <sup>1</sup>
200-519	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408	FLORVIO (florfenicol) 2.3% Concentrate Solution	Original approval as a generic copy of NADA 141-206	520.995	yes	CE <sup>1</sup>
200-547	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	ZILMAX (zilpaterol hydrochloride) plus RUMENSIN (monensin USP) plus TYLOVET 100 (tylosin phosphate) Type A medicated articles	Original approval as a generic copy of NADA 141-276	558.665	yes	CE <sup>1</sup>
200-555	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410	LIBREVIA (carprofen) Soft Chewable Tablets	Original approval as a generic copy of NADA 141-111	520.309	yes	CE <sup>1</sup>

<sup>1</sup>The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

## List of Subjects

### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

### 21 CFR Parts 520 and 524

Animal drugs.

### 21 CFR Part 556

Animal drugs, Foods.

### 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 524, 556, and 558 are amended as follows:

#### PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “Purina Nutrition LLC”, and alphabetically add entries for “Piedmont Animal Health” and “Purina Animal Nutrition LLC”; and in the table in paragraph (c)(2), in the entry for “017800”, remove “Purina Nutrition” and in its place add “Purina Animal Nutrition”, and numerically add an entry for “058147” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
* * * * *	
Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410	058147
* * * * *	
Purina Animal Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126-2910	017800
* * * * *	

(2) \* \* \*

Drug labeler code	Firm name and address
* * * * *	
058147	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410
* * * * *	

## PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.309 [Amended]

4. In paragraph (b)(2) of § 520.309, remove “Nos. 000115, 055529, and 062250” and in its place add “Nos. 000115, 055529, 058147, and 062250”.

5. In § 520.812, revise paragraphs (a) and (b) to read as follows:

§ 520.812 Enrofloxacin.

(a) Specifications. Each tablet contains:

(1) 22.7, 68.0, or 136.0 milligrams (mg) enrofloxacin; or

(2) 22.7, 68.0, 136.0, or 272 mg enrofloxacin.

(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) Nos. 000859 and 026637 for use of product described in paragraph (a)(1) of this section.

(2) No. 058198 for use of product described in paragraph (a)(2) of this section.

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§ 520.955 [Amended]

6. In paragraph (b) of § 520.955, remove “No. 000061” and in its place add “Nos. 000061 and 058198”.

#### PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

7. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1465 [Amended]

8. In paragraph (b) of § 524.1465, add “026637,” after “025463,”.

#### PART 556--TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

9. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.733 [Amended]

10. In paragraph (a) of § 556.733, remove “10 micrograms” and in its place add “50 micrograms”.

## PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

11. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

12. In § 558.665, in the table, revise paragraph (e)(5) to read as follows:

§ 558.665 Zilpaterol.

\* \* \* \* \*

(e) \* \* \*

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(5) 6.8 to provide 60 to 90 mg/head/day	Monensin 10 to 40, plus tylosin 8 to 10	Cattle fed in confinement for slaughter: As in paragraph (e)(1) of this section; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium (Actinomyces) pyogenes</i> .	As in paragraph (e)(1) of this section; see §§ 558.355(d) and 558.625(c) of this chapter. Monensin as provided by No. 000986; tylosin as provided by Nos. 000986 or 016592 in § 510.600(c) of this chapter	000061 016592
*	*	*	*	*

Dated: August 19, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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